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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,703	02/02/2000	KENJI SAKAMOTO	IKU0102PUSA	1461

22045 7590 11/26/2003

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/26/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/269,703

Applicant(s)
Sakamoto

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 8, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) 3-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1) Claims 1 to 15 are pending in the instant application.

2) Claims 3 to 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 23. The traversal is on the ground(s) that Group I and II are both classified in Class 435. This is not found persuasive because classification includes both a class and a subclass and inventions I and II are classified in different subclasses. M.P.E.P. 803 states that:

“ For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant.”

Serious burden was shown in the original requirement by the separate classification and separate status in the art of the different inventions. Applicant has provided neither a showing or evidence to the contrary. Further, Applicant is advised that “financial burden” is not a valid basis for traversing a proper restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5) The instant specification stands objected to for those reasons of record in section 4 of Paper Number 19. Applicant is advised that the substitute specification that was filed on 13 November of 2002 has not been entered because it did not include a certificate of verification of the accuracy of the translation. Whereas the correspondence to which that substitute specification was attached asserts that such a certificate was included therewith, no such certificate is present in the instant application. Correction is required.

6) Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims. These claims encompass a process of identifying a "physiologically active" peptide by producing a specific peptide and "testing" it "for physiological activity". The limitation "physiological activity" encompasses an almost unlimited range of potential biological activities, many of which are not mediated by receptors. The only "physiological activity" described in the instant specification is the ability of a peptide of the instant invention to agonize or antagonize the ligand-activation of the receptor from which it was derived. Because the instant specification does not identify other specific activities which might be associated with a peptide of the instant invention it leaves it to the artisan to identify any other "physiological activity" for that peptide by engaging in the substantial amount of undue experimentation and inventive contribution that would be required to test that peptide for any and all physiological activities. A patent is granted for a completed invention, not the general

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suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

The instant specification is not enabling because one can not following the guidance presented therein and practice the full scope of the claimed method without first making a substantial inventive contribution.

7) Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1) These claims are vague and indefinite because the term “the receptor being a receptor of a substance when there is present in vivo a substance or cell which has functional antagonism against the ligand for the receptor, or the receptor being a receptor of substance A wherein there is present in vivo a cell or substance which has a functional antagonism to cells on

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which the substance A causes an effect” is unintelligible. This language is clearly a very poor literal translation from a Japanese document and makes no sense in this form.

7.2) Claim 1 is vague and indefinite because there is no clear antecedent basis for the first occurrence of the limitation “the receptor”. This claim is also vague and indefinite because there is no clear antecedent basis for the limitation “the ligand for the receptor” since most, if not all, receptors bind to more than one ligand. There is clear antecedent basis for “the identical ligand” or “said identical ligand” but neither of these limitations has been employed. This claim is also vague and indefinite because there is no clear antecedent basis for “which domain” “is missing” since the claim does not require a missing domain. Claim 2 is vague and indefinite in so far as it depends from claim 1 for these elements.

8) A claim drawn to:

“A method of identifying a peptide as a receptor agonist or antagonist, said method comprising the steps of:

identifying a receptor that naturally occurs in two or more forms differing from one another in the length of their respective amino acid sequences, said differing receptor forms being receptive of a common ligand and being alternate products of a common gene;

identifying a domain that is present in the amino acid sequence of a larger form of said receptor but absent from the amino acid sequence of a smaller form of said receptor;

synthesizing a peptide consisting of the amino acid sequence of said domain; and

testing said peptide for agonistic or antagonistic activity towards said receptor or said common ligand.”

would be allowable if submitted.

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9) Applicant's arguments filed 13 November of 2002 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800